K110980

JUN 20 2011

510(k) Summary – Levitronix CentriMag Return Cannula Kit

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations, Part 807, and in particular §807.92.

A. Application Information

Date Prepared:	April 6, 2011
Submitter's Name & Address:	Levitronix LLC 45 First Avenue Waltham, MA 02451
Contact Person:	Lydia Sakakeeny, Ph.D. Regulatory Affairs Specialist Ph: (781) 466-6553 Fax: (781) 622-5090 e-mail: lsakakeeny@levitronix-us.com

B. Device Information

Trade or Proprietary Name:	CentriMag Return Cannula Kit
Common or Usual Name:	CentriMag Return Cannula Kit
Classification Name:	Catheter, cannula and tubing, vascular, cardiopulmonary bypass (DWF, 870.4210), Class II
Performance Standard:	Performance standards do not currently exist for these devices. None are established under section 514 of the Food, Drug and Cosmetic Act.

C. Legally Marketed Predicate Device

Levitronix Device	Predicate	Predicate 510(k)
CentriMag Return Cannula Kit	Medtronic EOPA™ Elongate one-piece Arterial Cannula and Guidewire (Medtronic EOPA 77722)	K031037

D. Device Description

CentriMag Return Cannula Kit

The CentriMag Return Cannula Kit consists of a sterile, single-use, disposable, non-coated, Polyvinyl Chloride (PVC) Cannula and the following accessories:

- *A) One Obturator (or Introducer)*
- *B) One Hemostasis Seal*
- *C) One Cap*
- *D) One Porous Plug*
- *E) One Needle with Sheath*
- *F) One Guidewire Assembly*
- *G) Two Stabilizer Rings – Medium*
- *H) Two Stabilizer Rings – Small*
- *I) Two Tip Stabilizers*

E. Intended Use

The CentriMag Return Cannula is indicated for use as an arterial return cannula with an extracorporeal bypass circuit for extracorporeal circulatory support for periods up to six hours.

F. Comparison to Predicate Device

The CentriMag Return Cannula Kit has an indication for use, design features, and functional characteristics which are substantially equivalent to the predicate device. The device raises no new safety or effectiveness issues.

G. Summary of Performance Data

The CentriMag Return Cannula Kit has successfully undergone functional testing demonstrating substantial equivalence to the predicate device. The following functional testing was performed. All met pre-established acceptance criteria.

- Physical Testing
- Sterilization Validation
- Biocompatibility
- Shelf Life Studies
- Transportation
- Hemolysis (in vitro)
- Flow versus Pressure Drop

H. Clinical Performance

Clinical testing was not performed for the CentriMag Return Cannula Kit.

I. Conclusion

The Levitronix CentriMag Return Cannula Kit is substantially equivalent to the Medtronic EOPA™ Elongate one-piece Arterial Cannula and Guidewire (K031037).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Levitronix LLC
c/o Lydia Sakakeeny, Ph.D.
Regulatory Affairs Specialist
45 First Avenue
Waltham, MA 02451

JUN 2 0 2011

Re: K110980
CENTRIMAG® Return Cannula Kit
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheters, cannula, or tubing
Regulatory Class: Class II (two)
Product Code: DWF
Dated: April 6, 2011
Received: April 7, 2011

Dear Dr. Sakakeeny:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Applicant: **Levitronix LLC**

510(k) Number (if known): K110980

Device Name: **CentriMag Return Cannula Kit**

Indications for Use:

The CentriMag Return Cannula is indicated for use as an arterial return cannula with an extracorporeal bypass circuit for extracorporeal circulatory support for periods up to six hours.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K110980